

REMARKS

Claims 1-16 are pending in the present application, claims 1, 2, 4, and 6 are under examination, claims 3, 5, and 7-9 are withdrawn as drawn to an unelected invention and claims 10-16 are cancelled. Upon entry of the present Amendment, claims 1-9 are pending and claims 1, 2, 4 and 6 are under examination.

Applicant notes that claims 3, 5, and 7-9 are drawn to unelected species; Applicant respectfully submits that these claims define a reasonable number of species and should be examined following a determination that the examined species are patentable. *See* 37 C.F.R. § 1.146.

I. The Amendments to the Claims

In the present paper, claims 1-3 are amended and claims 10-16 are cancelled without prejudice to Applicants' right to pursue the cancelled subject matter in one or more related continuation, divisional, or continuation-in-part applications.

The amendments to the claims are fully supported by the application as filed and therefore present no new matter. In particular, the amendments to claims 1-3 are supported, for example, by claims 1-3, respectively, as originally filed. As the amendments to the claims are fully supported by the application as filed, they present no new matter. Entry of the amendments to the claims are therefore respectfully requested under 37 C.F.R. § 1.111.

II. The Rejections under 35 U.S.C. § 103(a)

Claims 1, 2, 4, and 6 stand rejected as allegedly obvious under 35 U.S.C. § 103(a) over U.S. Patent No. 5,998,376 ("the '376 patent") and over Robledo and Witten, 1999, *Am. J. Physiol.* 276 (*Lung Cell. Mol. Physiol.* 20) L229-L238 ("Robledo"). In particular, the PTO urges that the instant claims are obvious over the '376 patent based on its teaching that aerosolized substance P analogs can be used to treat disorders resulting from exposure to jet fuel, including, for example, viral disorders. Similarly, the PTO argues that the present claims are obvious over Robledo based on its teaching that Sar⁹, Met (O₂)¹¹-Substance P was useful in mitigating lung injury caused by exposure to jet fuel.

In response, Applicants respectfully submit that neither reference, whether considered alone or in combination, teaches or suggests a method for treating SARS or ARDS as recited by the pending claims. Further, neither reference, whether considered alone or in

combination, provides a reason to modify the teachings of the references to obtain the invention defined by the pending claims.

A. Legal Standard

The Supreme Court’s decision in *KSR Int’l Co. v. Teleflex*, 127 S.Ct. 1727, (2007) provides guidance regarding exactly how the differences between the prior art and claimed invention are analyzed to assess the obviousness or non-obviousness of the claims. As the Supreme Court explained, “interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art” can all be assessed “to determine whether there was an apparent reason to combine the known elements” as recited by the claim at issue. *See id.* at 1731. “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* at 1741; *See also* M.P.E.P. § 2141 (8th Ed., Rev. 6, Sept. 2007). Accordingly, the Patent Office must “identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in a way the claimed new invention does.” *Id.*

As emphasized by the Federal Circuit since the *KSR* decision, the pharmaceutical arts are notoriously unpredictable, such that the ordinarily-skilled artisan cannot routinely predict what the effects of a pharmaceutical compound might be. For example, *Takeda Chemical Industries, LTD v. Alphapharm Pty, Ltd.*, 83 USPQ2d 1169 (Fed. Cir. 2007) not only clearly stated that the PTO must identify explicit portions of the reference that suggest the invention but also pointed out the unpredictability of the pharmaceutical arts. *See Takeda* at 1169. Similarly, *Eisai Co. Ltd. v. Dr. Reddy’s Laboratories, Ltd.*, 87 USPQ2d 1452 (Fed. Cir. 2008) held that the art must provide an explicit teaching and provide an expectation of success. *See Eisai* at 1452.

B. Neither Reference Teaches or Suggests a Method for Treating SARS or ARDS

Neither the ’376 patent nor Robledo teaches or suggests the specific method for treating SARS or ARDS recited by the pending claims. In particular, the ’376 patent and Robledo focuses generally on stimulation of the immune system and treating viral diseases in general. While the ’376 patent might suggest that Substance P or Substance P analogs might be useful in stimulating the immune system against viral diseases, nothing in the ’376 patent specifically suggests that Substance P or Substance P analogs might be useful in the treatment of the specific viral disease SARS. Given the unique nature of the specific viral agent that

causes SARS and the unpredictability of treatment of disease and the vast number of diseases caused by viruses, Applicant respectfully submits selection of SARS or ARDS as a disease to be treated could not be predicted based on the disclosure of the '376 patent.

Likewise, Robledo focuses on mitigation of damage caused by exposure to jet fuel. While Robledo teaches that Substance P analogs might be useful in ameliorating damage caused by jet fuel, it provides no indication that Substance P or Substance P analogs might be useful in the treatment any viral disease, let alone SARS or the condition of ARDS. Thus, like the '376 patent, Robledo fails to specifically teach or suggest a method for treating SARS or ARDS as recited by the pending claims. As such, neither of the references, whether considered alone or in combination, teaches or suggests the claimed subject matter.

Moreover, the PTO has not identified from either the '376 patent or Robledo a reason why one of ordinary skill in the art would be led from the teachings of the cited references to perform the claimed methods. As the Supreme Court specifically cautioned, the PTO must identify a reason why the artisan of ordinary skill would be led to modify the teaching of the prior art to obtain the claimed methods. *See KSR* at 1731. Absent such a reason to modify the teaching of the prior art, the PTO cannot establish *prima facie* obviousness of the claims.

In view of the foregoing, Applicant respectfully submits that claims 1, 2, 4, and 6 are not obvious under 35 U.S.C. § 103(a) the '376 patent or over Robledo. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejections.

CONCLUSION

No fee is believed due in connection with this response. However, should the Commissioner determine otherwise, he is hereby authorized to charge any required fee(s) to Jones Day Deposit Account No. 50-3013 (reference no.: 876946-999021).

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Respectfully submitted,

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